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Robotic partial nephrectomy – Evaluation of the impact of case mix on the procedural learning curve

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ROBOTIC PARTIAL NEPHRECTOMY – EVALUATION OF THE IMPACT OF CASE MIX ON THE PROCEDURAL LEARNING CURVE

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ROBOTIC PARTIAL NEPHRECTOMY – EVALUATION OF THE IMPACT OF CASE MIX ON THE PROCEDURAL LEARNING CURVE

Abstract

INTRODUCTION: Although Robotic partial nephrectomy (RPN) is an emerging technique for the management of small renal masses, this approach is technically demanding. To date, there is limited data on the nature and progression of the learning curve in RPN.

AIMS: To analyse the impact of case mix on the RPN LC and to model the learning curve.

METHODS: The records of the first 100 RPN performed, were analysed at our institution that were carried out by a single surgeon (B.C) (June 2010-December 2013). Cases were split based on their Preoperative Aspects and Dimensions Used for an Anatomical (PADUA) score into the following groups: 6-7, 8-9 and >10. Using a split group (20 patients in each group) and incremental analysis, the mean, the curve of best fit and R^2 values were calculated for each group.

RESULTS: Of 100 patients (F:28, M:72), the mean age was 56.4±11.9 years. The number of patients in each PADUA score groups: 6-7, 8-9 and >10 were 61, 32 and 7 respectively. An increase in incidence of more complex cases throughout the cohort was evident within the 8-9 group (2010: 1 case, 2013: 16 cases). The learning process did not significantly affect the proxies used to assess surgical proficiency in this study (operative time and warm ischemia time).

CONCLUSIONS: Case difficulty is an important parameter that should be considered when evaluating procedural learning curves. There is not one well fitting model that can be used to model the learning curve. With increasing experience, clinicians tend to operate on more difficult cases.

KEYWORDS: robotic partial nephrectomy, learning curve.

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INTRODUCTION

Renal cancer represents a frequently diagnosed urological malignancy with approximately 10,000 new cases reported in 2010 in the UK [1]. With an increase in the availability of routine imaging, more incidental renal masses are being uncovered and hence, curative treatment in early stage disease is paramount and achievable. Since Gettman et al.'s landmark study, RPN was shown to be a practical and safe alternative to LPN in the management of small renal masses [2,3].

RPNs are technically demanding procedures that require speed and precision to achieve adequate tumour excision and rennoraphy [2]. The quality of RPN can be determined by the careful patient selection, hospital length of stay, complication rate, recurrence, disease free patient survival. Task efficacy is more difficult to assess; hence operative time (OT), and intra-operative complications are commonly used [4]. All these components put RPN into the category of technically challenging surgical procedures that requires structured training with objective assessment. It is important to identify and evaluate components that determine the learning curve of RPN.

Research into a surgeon's LC in RPN is beginning to emerge, yet remains inadequate. LCs of simple motor tasks can be easily modeled; however, each surgical case is a unique operation with its own set of risks and complications [5]. Assessment of a surgeon's LC is therefore paramount to expose any underlying effects the learning process may have on patient outcomes. To date, there has not been a study published that creates a model for LC of RPN.

This study will address these issues by: analysing the impact of case mix on the RPN LC and modeling the LC on an incremental basis.

SUBJECTS AND METHODS

A retrospective analysis of a prospective database was carried out to evaluate consecutive patients who underwent elective RPN for renal mass excision carried out by a single surgeon (B.C). Between June 2010 and December 2013, 100 RPNs were performed (BC). In the first year, 25% of potential cases were done using the robotic approach, 50% in the second year and 75% for the final years. Each case was assessed for complexity using the components of the PADUA score. The main domains of the PADUA score are as follows: Radius, Exophytic/Endophytic, Location, Renal rim, renal sinus and collecting system infiltration. Single kidney and poor renal function were contraindications during the first three years, but patients with these contraindications were included in the last year. Redo surgery, multiple tumours and people with Von Hippel-Lindau syndrome were all excluded and performed using an open approach. Variables of interest included: Age and gender, side of tumour, maximum tumour diameter, PADUA score components, WIT, OT and estimated blood loss (EBL), Length of stay (LoS), positive surgical margins (PSM) and complications (classified using the Clavian Scoring system). Patients were then categorised based on the year their operation was conducted into their respective PADUA score risk group.

Analyse the impact of case mix on the RPN LC

Preoperative Aspects and Dimensions Used for an Anatomical (PADUA) Score was used for risk assessment (total sum of the scores ranging between 6 and 13). Scores of 8-9 have been shown to have 14-fold risk and scores > 10 were associated with a 30-fold increase risk of complications compared to those patients reporting scores of 6 to 7 [6]. Patients were grouped into their PADUA risk score values: 6-7 (low risk), 8-9 (medium risk) and > 10 (high risk). The number of patients in each group was totaled for every year in the study.

Outcome measures

Outcome measures included warm ischaemia time, operating time and positive margins. Time was measured using the operating theatre computer data and the recording procedure was standard across the cases. Time points to first incision and that for the closure were recorded prospectively on the database. The time was recorded by the theatre nurses using the standard hospital software installed in the operating theatre computers.

Warm Ischaemia Time (WIT) was prospectively measured in seconds by the surgeon's digital clock, which was kept along the console for the length of each procedure.

Modeling the LC

Each patient's PADUA score risk group was plotted against the respective case series number and a line of best fit using the R^2 approach was applied to assess for any change in the case mix in the group. Comparisons of equations produced were carried out to assess for data loss in categorical analysis.

The following software packages were utilised: Statistical Package for the Social Science (SPSS), version 21.0 (SPSS, IBM, Armonk, NY, USA) and Excel 2010 (Microsoft, Redmond, WA, USA). Data assessed for normal distribution using the Shapiro-Wilk method of analysis. Parametric continuous variables are referred to as the mean ± their standard deviations (SD). The non-parametric continuous variables are referred to as median, alongside their interquartile range (IQR). Significance was set with $p = <0.05$.

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RESULTS

The baseline patient characteristics for each PADUA score category and their components are listed in Table 1. The number of patients undergoing RPN increased with each successive year. Most patients had a PADUA score of 6-7 (61/100). The number of cases in this category carried out over the course of a one-year period increased from 3 to 24 over the study period. The 1st RPN with PADUA score >10 was not carried out until early 2012.

Perioperative outcomes

The perioperative outcomes for each PADUA score category and their components are listed in Table 2. PSM were seen only in 2 cases across the series, both in the 6-7 category. These were both early on in the series in 2011 (case no. 10 and 13).

5 post-operative complications were seen: 3 in the low risk group and 2 in the medium risk group. There were 2 intra-operative conversions to radical nephrectomy after intra-operative assessment and without commencing partial nephrectomy, (case no. 24 and 89) due to the large endophytic nature of the tumours. There were no conversions to an open procedure or blood transfusions.

Analyse the impact of case mix on the RPN LC

Fig. 1 demarcates the increase in incidence of more complex cases throughout the cohort. In the first year, collectively there were 4 procedures carried out, of which only one was a medium risk PADUA.

Over the 4-year period there has been a rise in the number of more complex cases being carried out throughout series.

Warm ischemia time

The mean WIT for each PADUA score is summarised in table 3. The WIT does not vary greatly across the PADUA score groups. Fig. 2(a) depicts the line of best fit for the incremental analysis and Fig. 2(b) demonstrates the categorical analysis with their associated R^2 values for each PADUA score risk group.

Operative time

The mean OT for each PADUA score is summarised in Table 2. Fig. 3(a) depicts the line of best fit for the incremental analysis and Fig. 3(b) demonstrates the categorical analysis with their associated R^2 values for each PADUA score risk group.

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DISCUSSION

This article demonstrates that the learning process does not pointedly affect the proxies of surgical proficiency; OT, WIT and the clinical outcomes measured. Fig 1 clearly illustrates a shift towards more complex cases towards the later years of the series, which can be seen as a part of continual surgical development allied with concurrent negligible change in the operative measures and clinical outcomes. This can be attributed to the expansion of the selection criteria that developed over the years. All the values for the WIT except one (case 42), were under 30 minutes (65 % ≤ 20 minutes and 96% ≤ 25 minutes) and when referring back to the WIT required to minimise renal functional decline post-operatively, then the learning process did not impinge on this metric measured and the same can be said for the OT. With respect to modeling the curve, the R^2 values were all too low to adequately create a model for the LC for this procedure using the parameters assessed.

Previous studies have suggested that LC length ranges between 5 and 36, however this is rather dependent on their definition of a LC. There have been various methods used in the literature to measure the LC. These include outcome measures (peri-operative and oncological), observation of performance in operating theatre with a plot of objective assessment. With each of these definitions, the number of cases required to overcome the LC with this data series can be seen to range from 20 to 65 when exercising commonly used definitions of proficiency . Partial nephrectomy is a challenging surgical procedure. Wide variations exist due to tumour location and patient related factors. Surgeons tend to do progressively more difficult cases with time as their experience increases. This has been highlighted in this study and that is the main reason we have used risk assessment nephrometry scores for a staged analysis of the learning curve.

Our study is not without its limitations. Our dataset only included the first 100 RPN cases, which a rather small number of cases compared with other series such as those in table 3. Furthermore, it was a retrospective analysis and is a limitation as the individuals who input the data changed leading to potential inconsistencies. We recommend prospective data collection for learning curve evaluation making sure all the variable are available for analysis. Learning curves should be evaluated using various outcome parameters such as operating time, warm ischaemia time, peri-operative complications and oncological outcomes. However, confounding factors such as case-difficulty, surgeon's experience should be considered in order to minimize bias.

Another potential factor that may have hindered a decrease in outcome measures that would have been expected could be the training of fellows that occurred towards the later quartile of the case series. They may be involved in portions of the cases, typically before and after WIT. This may have added to the OT. This was very difficult to integrate into the analysis as total time spent teaching during the operation is difficult to quantify. Finally there is an element of selection bias, given the inclusion and exclusion criteria over the course of the study.

Further work can investigate the long-term outcomes of these patients compared with previous treatment options. Finally, multi-centre studies are required to ensure these parameters and results are reproducible.

CONCLUSIONS

We found that the learning curve of RPN should be ongoing and hence there should not be a defined end point, nor can it be adequately modeled. When assessing the impact of case-mix on the learning curve, it has been demonstrated that it does not impact the parameters measured in this study (OT and WIT). Future studies with extended follow up are needed to further evaluate the long term efficacy and the LC effect in RPN due to the infancy of the technology and the variety of case complexity being undertaken with this technique.

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TABLES & FIGURES

Patient Demographics	PADUA SCORE		
	6-7	8-9	>10
Total number of patients	61	32	7
Age (Mean ± SD)	56.5 ± 11.7	56.3 ± 13.0	58.0 ± 0.3
Male patients (%)	40/61 (66)	27/32 (85)	5/7 (71)
Tumour side (% Right sided)	29/61 (47)	13/32 (40)	2/7 (29)
Max tumour diameter (cm)	2.6	3.3	3.3

Table 1: Baseline patient demographic data

Operative and post-operative	6-7	8-9	>10
OT (mins)	186 ± 75	150 ± 35	193 ± 16
WIT (mins)	18 ± 4	18 ± 5	21 ± 3
WIT <30 mins (%)	100%	100%	100%
EBL (ml)	153 ± 122	131 ± 95	169 ± 122
LoS	3 ± 1	3 ± 1	4 ± 1
Creatinine change	-4 ± 11	-14 ± 23	-14 ± 27
Clavien Type 1	1 (wound infection)	2 (basal atelectasis and 1 wound infection)	0
Clavien Type 2	1 (urinary retention)	0	0
Clavien Type 3	1 (stent insertion IIIa)	0	0
PSM	2	0	0
Mortality	0	0	0

Table 2: Peri-operative data

Author	No. of surgeons	Institution	Year	Definition of learning curve	Number of cases required	Patients in study	Number of cases required in our cohort
Benway et al, [7]	1	USA	2009	Reaching maximal overall efficiency and maximum efficiency for portions of the case performed under warm ischemia, which include tumor dissection and renorrhaphy	WIT: 19 OT: 26	50	WIT: 65 OT: 60
Haseebuddin et al, [8]	1	USA	2010	Number of cases after which minimal variation of WIT and overall OT was observed, as identified by a levelling of the slope of the curve	WIT: 26 OT: 16	38	WIT: 31 OT: 30
Mottrie et al, [5]	1	Belgium	2010	Median WIT: < 20 mins Median Console Time:<100 mins	WIT: 30 Console time: 20	62	WIT: 20
Dulabon et al, [9]	4	Multi-Institution	2011	No formal definition given, but reference to WIT and conversion rates	WIT for hilar cohort didn't decrease with more recent years conversions rates were similar throughout	446	NA
Lavery et al, [10]	1	USA	2011	Number of cases required to consistently perform RPN with equal or shorter average OT and WIT than the average of the last 18 LPN	WIT: 5 OT: 5	40	NA
Petros et al, [11]	4	Multi-Institution	2012	Surrogate end points such as the proportion of tumors > 4 cm attempted, positive surgical margins, and WIT	No significant change between first and second half of the study	445	No significant change between first and second half of the study
Faria et al, [3]	1	USA	2014	The number of cases required to consistently perform RPN with WIT, as compared to the end of LPN series	WIT: 40 OT: Not mentioned	137	NA

Table 3. Examples definitions for the LC

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Author	Year	Institution	Patient Number	Data Organisation	Statistical Method	Group Size	Parameters	Curve described	Results of statistical testing
Faria *et al.* [3]	2014	University of Texas	137	NA	Linear regression	NA	WIT	Linear regression line	
Petros *et al.* [11]	2012	Multi-institutional	445	Split group – 2 groups	Student-t-test	223 & 222	WIT, PSM, OT	No Curve	No difference between groups in WIT & PSM. But shorter OT (189 vs 175 mins) p = < 0.05
Laverly *et al.* [10]	2011	New York	20	Each case was plotted at its respective date	R^2 line of best fit was applied	20	OT	Cubic	$R^2 = 0.32$ $R^2 = 0.18$ for linear model $R^2 = 0.30$ for quadratic line
Dulabon *et al.* [9]	2010	Multi-institutional	446	Not mentioned	Not mentioned	Not mentioned	WIT	None	None
Haseebuddin *et al.* [8]	2010	Washington	38	Each case was assigned a consecutive number	Polynomial regression	38	WIT, OT	Polynomial regression line	No mention of curve type
Mottrie *et al.* [5]	2010	Belgium	62	Split group – 6 groups	Student t test	10	WIT, CT	None	Surgeon experience significantly correlated to CT & WIT (p=<0.001 & p=<0.0001)

Table 4: Examples for statistical analysis performed to assess the LC

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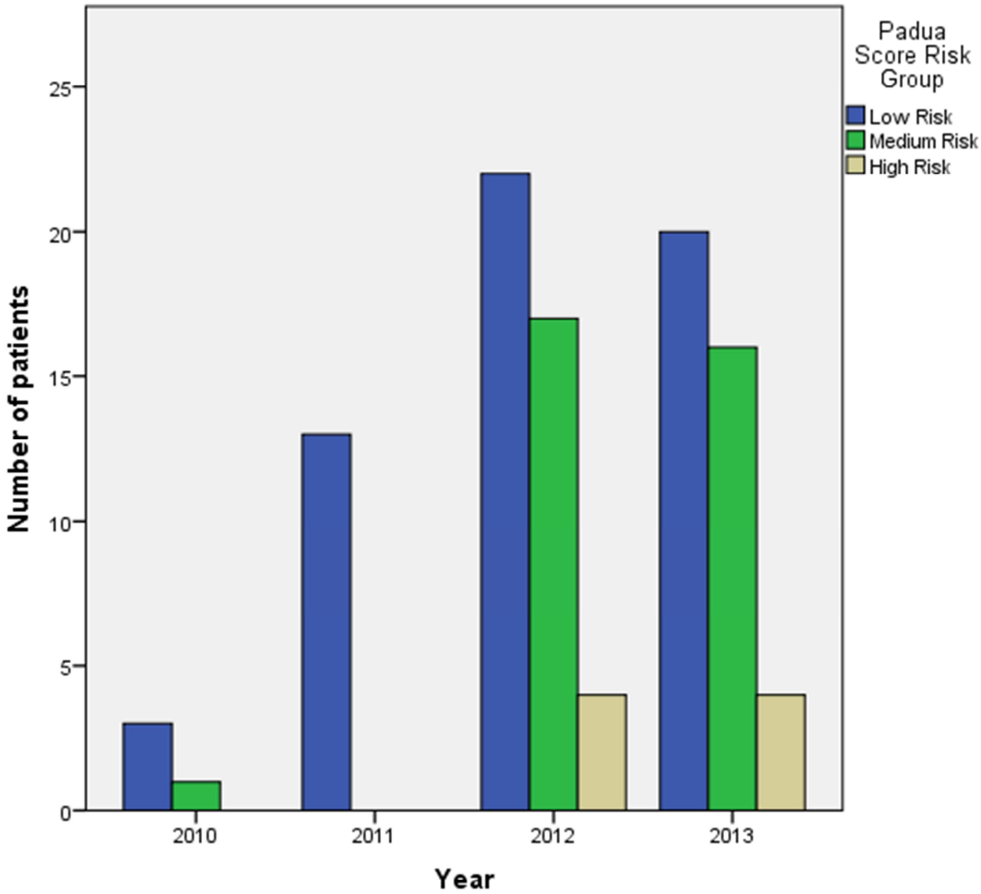

Fig. 1: A bar chart illustrating the number of patients in each PADUA score risk group over the years in the series.

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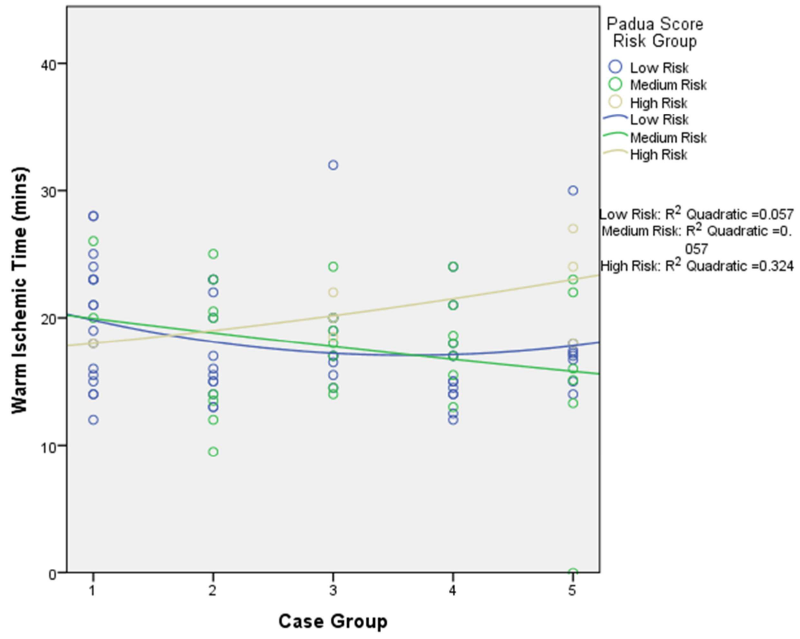

Fig. 2(a): A graph showing WIT vs the case series in incremental series using a Quadratic Model.

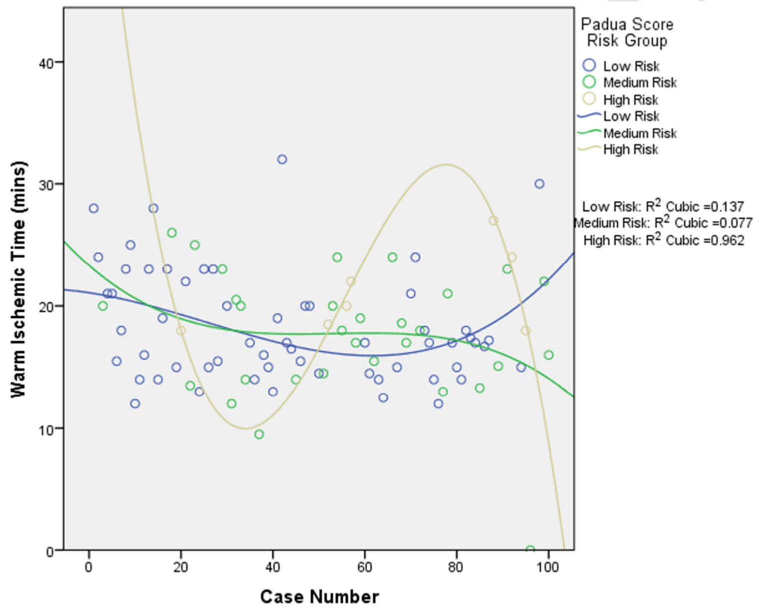

Fig. 2(b): A scatter graph showing WIT vs the case series in categorical series using a Cubic Model.

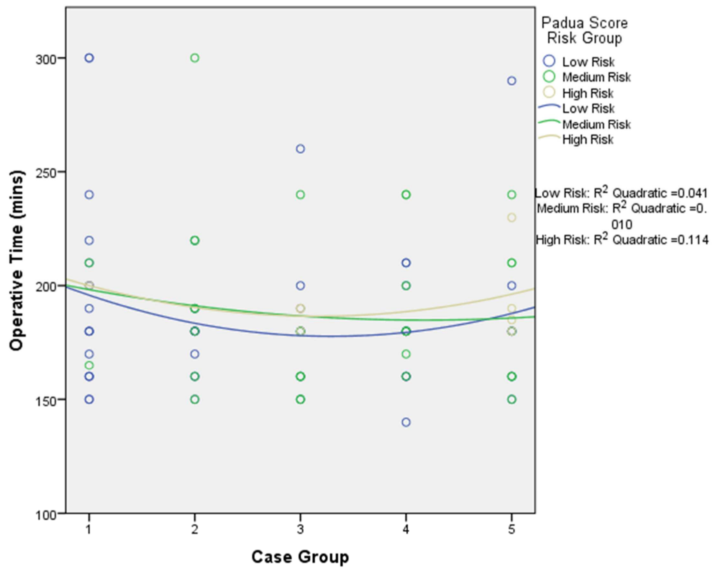

Fig. 3(a): A graph showing OT vs the case series in incremental series using a Cubic Model.

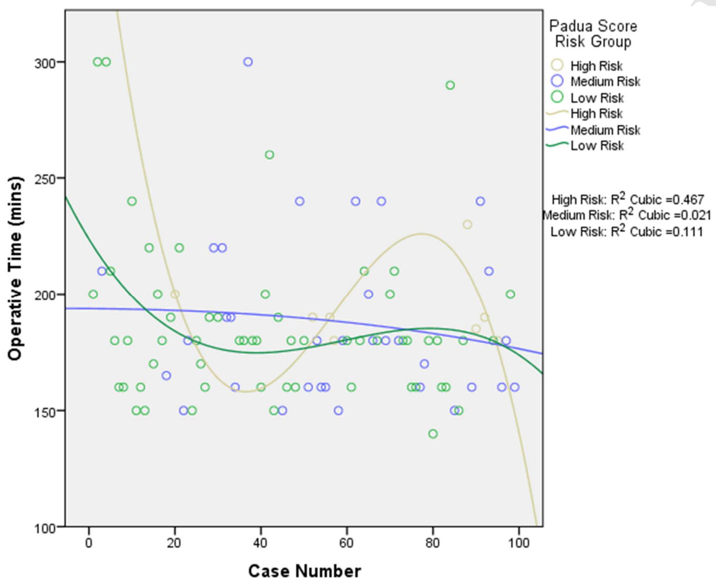

Fig. 3(b): A Scatter graph showing OT vs the case series in categorical series using a Quadratic Model.

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HIGHLIGHTS

The evaluation of 100 robotic partial nephrectomies carried out by a single surgeon. The learning process did not affect the proxies used to assess surgical proficiency. More complex cases were taken on throughout the cohort. Case difficulty should be considered when evaluating procedural learning curves.

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